


TSCA NON-CONFIDENTIAL BUSINESS INFORMATION**DOCUMENT
DESCRIPTION****DOCUMENT
CONTROL N^o****DATE RECEIVED**

PC4859

COMMENTS:

MC = 301 R&D **DOES NOT CONTAIN CBI**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr Bob Fensterheim
RegNet Environmental Services
1250 Connecticut Avenue, North West, #700
Washington, DC 20036

CONTAINS NO
CBI

Re: PC-4859

Dear Mr. Fensterheim:

This letter responds to your letter dated 30 September 2004, and sent to Dave Schutz of my staff, in which you asked that the Agency provide a written opinion on whether your client's use and sale of a polymer substance which does not meet the requirements of the polymer exemption can be permitted under the research and development ('R&D') exemption from the requirement under the Toxic Substances Control Act ('TSCA') that premanufacture notification ('PMN') be filed for commercial use of a new chemical substance not included in the TSCA Inventory of chemical substances.

In your letter, you describe your situation as follows: your client's material would be utilized to enable analytical component separations in chemical mixtures and comparative quantitation of such components for activities including development of new chemicals and assays of chemicals and product quality control and related process control. Your letter asked that the Agency concur with your understanding that the material can meet the conditions for exemption from premanufacture notification ("PMN") under §5 of the TSCA described at 40 Code of Federal Regulations ("CFR") §§720.36 and 78 ('the R&D exemption'), both in a laboratory setting and in an online production process control setting, with the understanding that when used outside of a laboratory using prudent practices it must be under the supervision of a technically qualified individual.

Chemical substances used exclusively for R&D are eligible for the R&D exemption under 40CFR §§720.36 and 78 if their manufacturers meet all the requirements associated with the exemption. The substance must either be the focus of R&D itself, or be used in an R&D activity focusing on another chemical substance. The latter category encompasses reagents, chemicals to be used as standards for chemical analysis in laboratories, and intermediates used solely to produce R&D substances, including intermediates used in the production of pesticides used exclusively for R&D. Based on your discussion of the use of your material, it is being used as a reagent, so can qualify for the R&D exemption. As you noted in your letter, you need not apply to the Agency for permission to use the R&D exemption. However, it is your responsibility to determine that your use is consistent with the exemption and to keep adequate records of your determination and your use which conform to the requirements at 40CFR §720.78. The required records are summarized in the table below. Manufacturers must keep records documenting compliance with the requirements imposed by the exemption for 5 years.

In addition to the specific records required by the rule, manufacturers and processors who conclude they are exempt from section 5(a) notice requirements for a chemical substance used for purposes of R&D should be prepared to justify the nature and scope of their activities. They bear the burden of proving their eligibility for the R&D exemption, should a question arise concerning their compliance with the general requirements for PMN, a SNUR, or the exemption for R&D.

You have not indicated an intent to use your polymer substance at levels greater than 10,000 kilograms/year. You may want to consider whether a Low Volume Exemption (our threshold for an LVE is use of less than 10,000 kg/year) would serve your needs better than would reliance on the R&D exemption. An LVE would require substantially less record-keeping than use of the R&D exemption, there is no fee for application for an LVE, and we make our determinations on applications for LVE within 30 days of receipt. If you want to consider using your material under an LVE, or if you have other questions about this letter, please view www.epa.gov/opptintr/newchems/whofiles.htm#exempt or contact Dave Schutz of my staff. I hope this discussion adequately addresses your concerns. If you have remaining questions, feel free to contact Mr. Schutz on 202-564-9262.

Sincerely Yours,

A handwritten signature in cursive script, appearing to read "Linda Gerber".

Linda Gerber, Chief
New Chemicals Prenotice Branch
Chemical Control Division (7405)

Mr Bob Fensterheim
RegNet Environmental Services
1250 Connecticut Avenue, North West, #700
Washington, DC 20036

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CONCURRENCE		
SYMBOL	7405	7405
SURNAME	Schutz <i>[Signature]</i>	Gerber <i>[Signature]</i>
DATE	21 Oct 2004	10/25/04

1320-1A

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REGNET

REGNET ENVIRONMENTAL SERVICES

September 30, 2004

Mr. David Schutz
Environmental Protection Agency
7405M
1200 Pennsylvania Avenue, NW
Washington, DC 20460
schutz.david@epa.gov

Dear David:

Thanks for speaking with me last week about the relevance of the TSCA R&D exemption as it pertains to the analysis of chemical substances. I would greatly appreciate if you could confirm in writing the interpretation described below, as I believe this is consistent with our discussion.

Definition of R&D

According to TSCA section 5(h)(3), the new substance notification requirements of section 5(a) do not apply to manufacturers and processors of chemical substances, if they manufacture or process the substances solely for purposes of:

... chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product, ...

EPA regulations codified at 40 CFR 720.36 exempts from the TSCA Inventory/Premanufacture Notification requirements, chemical substances manufactured "solely for research and development." The November 1986 Bulletin on Exemptions for Research and Development and Test Marketing, states that R&D includes:

- Synthesis of new chemical stances
- Analysis, experimentation or research on new or existing chemical substances.

The document notes that "R&D focuses on the analysis of the chemical or physical characteristics, the performance, or the production characteristics of a chemical substance, a mixture containing the substance or an article." The document goes on to identify examples of R&D activities including:

- ... physical/chemical properties testing in the laboratory
- Tests or demonstrations of equipment or production processes...

- Efficacy and performance tests...

The document also clarifies that the "general" distribution of chemical substances does not constitute R&D.

Specific Question

The circumstance I am addressing concerns the applicability of the R&D exemption for a polymer, that is not listed on the TSCA Inventory and does not meet the polymer exemption, if the polymer's sole use is in the conduct of analysis of other compounds. Specifically, the polymer would be utilized to enable analytical component separations in chemical mixtures and comparative quantitation of such components (from small to very large molecules) for activities including:

- Developing new chemicals or new assays for chemicals
- Product quality control and related process control in chemical production.

My review of the TSCA requirements suggests that the R&D exemption is applicable and as such no PMN is needed in order to manufacture and use the new polymer in the conduct of analytical work, so long as all of the provisions of the R&D exemption are followed. Moreover, my review suggests that the R&D exemption is applicable if the substance is used in a laboratory setting as well as if the analysis occurs in an on-line production process control setting so long as the activities are under the supervision of personnel appropriately trained in the responsibilities and methods for correct handling and disposal of chemicals.

I further assume that such R&D exemption would apply even when the exempted product is incorporated by a third party into specific quality control products (*e.g.*, buffer systems) sold for process and product quality control applications as these would fall under the R&D exemption.

I would greatly appreciate if you would confirm my assessment. Please do not hesitate to contact me if I can provide any further clarification.

Sincerely,

Robert J. Fensterheim